**Title**

# Characteristics of European adults who dropped out from the Food4Me internet-based personalised nutrition intervention

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**Ethical standards disclosure:** This study was conducted according to the guidelines laid down in the Declaration of Helsinki and all procedures involving human subjects/patients were approved by the Research Ethics Committees at each University or Research Centre delivering the intervention. The Food4Me trial was registered as a RCT (NCT01530139) at Clinicaltrials.gov. All participants expressing an interest in the study were asked to sign online consent forms at two stages in the screening process. These consent forms were automatically directed to the local study investigators to be counter-signed and archived.

**Abstract (words count=248)**

**Objective**

To characterise participants who dropped out of the Food4Me Proof of Principle study.

**Design**

The Food4Me study was an internet-based, 6-month, 4-arm, randomized controlled trial. The control group received generalised dietary and lifestyle recommendations, whereas participants randomised to three different levels of PN (personalised nutrition) received advice based on dietary, phenotypic and/or genotypic data respectively (with either more or less frequent feedback).

**Setting**

Seven recruitment sites: the UK, Ireland, the Netherlands, Germany, Spain, Poland and Greece.

**Subjects**

Adults aged 18-79 years (*n* 1607).

**Results**

A total of 337 (21%) participants dropped out during the intervention. At baseline, dropouts had higher BMI (0.5kg/$m^2$; $P<0.001$). Attrition did not differ significantly between individuals receiving generalised dietary guidelines (Control) and those randomized to PN. Participants were more likely to drop out if they received more frequent feedback (OR: 1.81, CI: 1.36-2.41; $P<0.001$), if they were female (1.38, 1.06-1.78; $P=0.015$), less than 45 years of age (2.57, 1.95-3.39; $P<0.001$) and obese (2.25, 1.47-3.43; $P<0.001$). Attrition was more likely in participants who reported an interest in losing weight (1.53, 1.19-1.97; $P<0.001$) or skipping meals (1.75 (1.16-2.65; $P=0.008$), and less likely if they claimed to eat healthily frequently (0.62 (0.45-0.86); $P=0.003$).

**Conclusions**

Attrition did not differ between participants receiving generalised or PN advice but more frequent feedback was related to attrition for those randomized to PN interventions. Better

strategies are required to minimise dropouts among younger and obese individuals in those participating in PN interventions and more frequent feedback may be an unnecessary burden.

**Trial registration** – Clinicaltrials.gov NCT01530139

**Key Words**: Dropout; personalised nutrition; internet-based; European adults; Food4Me

## INTRODUCTION

Improving diet and physical activity behaviours are important means of lowering risk of non-communicable diseases, promoting healthy ageing and increasing well-being [1; 2]. Given that the burden of ill health is increasing [1; 3], alternative strategies for improving dietary behaviours, based on predictive, personalised, preventative and participatory interventions, may be more effective than conventional "one size fits all" generalised dietary advice [4; 5]. Personalised nutrition (PN) may be a more effective approach for improving dietary and physical activity behaviours than non-personalised advice [5; 6]. However, the relevance of the outcomes of PN interventions may be limited if there are systematic socio-demographic or behavioural differences between study completers and dropouts, which may result in specific target groups (e.g. obese individuals) not benefiting from PN. Socio-demographic variables such as age, social class, occupation, and financial factors are key determinants of dropouts in lifestyle-based interventions [7; 8], with more recent evidence also suggesting that behavioural characteristics are important predictors of attrition [9]. Dropouts from dietary and lifestyle interventions may differ considerably from one intervention to another [7], with approximately a third of participants dropping out of weight loss interventions [10; 11; 12; 13] and 20% from other diet and lifestyle interventions [7; 14]. For reasons of cost-effectiveness, reach and scalability, internet-based lifestyle interventions are increasingly popular [15; 16] although more information is needed on the characteristics of dropouts from such studies. Understanding the determinants of attrition from internet-based PN intervention studies will inform the design of more efficiently targeted lifestyle interventions.

The aim of the present paper was to characterise participants who dropped out of the Food4Me Proof of Principle (PoP) internet-based trial of PN, which was designed to improve dietary and physical activity behaviours. Socio-demographic, anthropometric, dietary, behavioural and health-related characteristics are compared between completers and those who dropped out.

## METHODS

### Study design

The Food4Me PoP study was a 6-month, 4-arm, internet-based, RCT conducted across 7 European countries via www.food4me.org [17]. The RCT was designed to emulate a real-life

internet-based PN service and aimed to investigate i) whether personalisation of dietary advice assists and/or motivates participants to eat a healthier diet in comparison with non-personalised, conventional healthy eating guidelines and ii) whether personalisation based on individualised phenotypic or genotypic information is more effective in assisting and/or motivating study participants to make, and to sustain, appropriate healthy changes, than personalisation based on diet alone. The Research Ethics Committees at each University or Research Centre delivering the intervention granted ethical approval for the study. The Food4Me trial was registered as a RCT (NCT01530139) at Clinicaltrials.gov. All participants expressing an interest in the study were asked to sign online consent forms at two stages in the screening process.

**Recruitment and eligibility criteria**

Participants were recruited via the Internet to emulate an internet-based PN service. This was aided by local and national advertising of the study via the Internet, radio, newspapers, posters, e-flyers, social media and word of mouth. Recruitment sites were as follows: University College Dublin (Ireland), Maastricht University (The Netherlands), University of Navarra (Spain), Harokopio University (Greece), University of Reading (United Kingdom, UK), National Food and Nutrition Institute (Poland) and Technical University of Munich (Germany). Participants were excluded if they were <18 years of age, pregnant or lactating, had no or limited access to the Internet, were following a prescribed diet for any reason, including weight loss, in the last 3 months or had diabetes, coeliac disease, Crohn's disease, or any metabolic disease or condition altering nutritional requirements such as thyroid disorders (if condition was not controlled), allergies or food intolerances. Participants were incentivised to join the study by receiving a personalised feedback report at month 6 based on their dietary, phenotypic and genotypic information, regardless of their treatment arm allocation.

**Intervention arms**

A total of 1607 participants were randomized to one of four intervention arms. Participants received non-personalised, generalised dietary and physical activity (PA) advice (Control), or one of three levels of PN: Level 1: based on personal current PA + diet alone; Level 2: based on PA + dietary and phenotypic data; Level 3: based on PA + dietary, phenotypic and

genotypic data. Participants randomized to levels 1, 2 or 3 were further randomized into “low intensity” or “high intensity” intervention groups. Participants in the low intensity group received personalised feedback three times during the intervention (at baseline, month 3 and month 6), whereas those randomized to the high intensity group received personalised feedback five times during the intervention (at baseline and months 1, 2, 3 and 6). In addition, the high intensity group had access to an online forum for discussion of topics related to the intervention, personalised recipes and had more personalised feedback on PA. Further details of the Food4Me PoP study are provided elsewhere [17].

**Personalized feedback report**

At baseline, month 3 and month 6, intakes of 5 food groups (fruits and vegetables, wholegrain, low-fat dairy products, oily fish and red meat and processed meat) and 17 nutrients were categorized as too high or too low for each participant randomised to PN. Contributing foods were identified and specific messages were developed, according to standardized algorithms, to advise change in intake of those foods. For participants randomized to L2 and L3, feedback also included phenotypic measures (L2) and phenotypic and genotypic data (L3) [17].

**Screening questionnaires and dietary intakes**

Individuals who were interested in participating in the study completed an online screening questionnaire to collect information on socio-demographic, health and anthropometric characteristics. This questionnaire also included information on dietary habits (e.g. meal skipping) and reasons for interest in participation in the study (e.g. weight loss). Likert scale responses were aggregated into three categories: ‘Disagree’ ('Completely disagree' and 'Disagree'), 'Neither disagree nor agree' and ‘Agree’ ('Agree' and 'Completely agree') and questions relating to frequency of the occurrence into two categories: Often ('Every day' and '4-6 times per week') or Rarely ('1-3 times per week' and '(almost) never'; **Supplemental Table 1**).

Participants were asked to complete an online food frequency questionnaire (FFQ) to estimate usual dietary intake at screening, baseline (month 0) and at months 3 and 6 (also at months 1 and 2 for the high intensity group only). This FFQ was developed and validated for the Food4Me Study [18; 19], and included 157 food items consumed frequently in each of the 7

recruitment countries. Intakes of foods, total energy and macronutrients were computed in real time using a food composition database based on McCance & Widdowson's "The composition of foods" [20]. Basal metabolic rate (BMR) was estimated using the Oxford equation [21]. Intakes were assessed using standardised recommendations [17] for foods and food groups that were integrated and harmonised across 8 European countries (UK, Ireland, Germany, The Netherlands, Spain, Greece, Poland and Norway) [22; 23; 24; 25]. The following 5 food group recommendations were used in the present analysis: eat at least 5 portions of fruits and vegetables every day (operationalised as ≥400g); eat at least 3 portions of wholegrain products daily (≥50g); eat at least 3 portions of low-fat dairy products daily (≥600g); eat at least 1 portion of oily fish per week (≥150g) and eat fewer than 3 portions of red meat and processed meat per week (≤450g) [17].

**Socio-demographic and health-related measures**

Body weight, height and waist circumference (WC) were self-measured and self-reported. Body mass index (BMI) was estimated from body weight and height. Self-reported measurements were validated in a sub-sample of the participants (*n*=140) and showed a high degree of reliability [26]. Participants were sent finger-prick based Dry Blood Spot cards (collected 5 drops equivalent to 150 µl of blood per card) which were completed and returned by post to recruitment centres and used to estimate total blood cholesterol concentrations. Physical activity levels (PALs) and time spent in sedentary behaviours (SB) were estimated from tri-axial accelerometers (TracmorD, Philips Consumer Lifestyle, The Netherlands). Participants self-reported smoking habits and occupation. Based on European classifications of occupations the following groupings were used: "Professional and managerial" (professionals; managers); "Intermediate" (armed forces occupations; technicians and associate professionals; clerical support workers); "Routine and manual" (craft and related trades workers; plant and machine operators and assemblers; service and sales workers; elementary occupations; skilled agricultural, forestry and fishery workers) [27; 28]. Categories for "Students" and "Retired and unemployed" were added. See Supplemental material for further information on the study design.

**Statistical analyses**

Data were analysed using Stata (version 13; StataCorp, College Station, TX, USA). Screening data (dietary habits, FFQ, reasons for interest in the study, ethnicity, medication use and health characteristics) plus measurements of WC, SB and PAL, which were collected at baseline, were used in the present analysis. Logistic regression and multiple linear regression were used to test for significant differences between categorical and continuous variables, respectively. The Odds Ratio (OR) for dropping out before month 6 was estimated for categorical variables. All analyses were adjusted for baseline age, sex and country. Physical activity outcomes were further adjusted for time spent wearing the accelerometer and season. Sensitivity analyses were performed to estimate ORs for dropping out at the interim time point (month 3). Results were deemed significant at $P<0.05$.

## RESULTS

A total of 1607 participants were randomized into the study at baseline. As summarised in **Figure 1**, 337 participants (21%) dropped out and 1270 participants completed the 6-month intervention period. Of the 337 participants dropped out, 127 (38%) dropped out before completing baseline measurements and a total of 261 (77%) had dropped out by month 3 (Fig 1).

### Health and lifestyle-related characteristics

Dropouts were on average 6 years younger than completers and were predominantly female (**Table 1**). In addition, dropouts weighed more, had higher BMI and lower WC (Table 1). More participants who dropped out of the study (8%), than those who completed, reported being interested in participating because they wanted to lose weight. No significant differences in occupation classification were observed between completers and those who dropped out. Furthermore, there were no significant differences in the height, PAL, SB or total cholesterol concentrations between groups. The percentage of individuals following a restricted diet, taking medication or presenting with clinically diagnosed diseases did not differ significantly between completers and dropouts (Table 1).

### Dietary characteristics

No significant differences in total energy intakes or energy intake (EI) to BMR ratio were identified between individuals who completed the 6–month intervention and those who dropped out (**Table 2**). Completers reported consuming more energy from polyunsaturated fatty acids (PUFA) and less salt than dropouts. Percentage energy intakes from total fat, saturated (SFA) and monounsaturated fatty acids (MUFA), protein and carbohydrate were not significantly different between dropouts and completers (Table 2). The percentage of individuals who met the dietary recommendations for oily fish, wholegrains, red meat, fruit and vegetables, and low-fat dairy products did not differ significantly between completers and dropouts (Table 2).

**Odds ratios of dropping out by intervention arm**

Attrition did not differ significantly depending on whether individuals were randomized to receive generalised dietary guidelines (Control) or any level of PN (L1, L2 or L3; **Table 3**). When levels of PN were grouped together (L1, L2 and L3), there was no significant difference in OR for dropping out between participants who received generalised dietary advice (Control) and those who received PN advice (Table 3). However, when intervention arms were grouped according to whether individuals received high or low intensity feedback, the odds of participants dropping out were higher in those randomised to receive high intensity feedback than low intensity feedback (OR 1.81, 95% CI: 1.36-2.41; $P<0.001$).

**Odds ratio of dropping out by socio-demographic and dietary characteristics**

Stratification by age revealed that the odds of participants dropping out were higher if they were under 45 y of age than if they were over 45 y (**Table 4**). In addition, the odds of females dropping out were higher than for males. Compared with normal weight individuals, the odds of dropping out were higher in obese individuals. Attrition was not significantly different in overweight compared with normal weight individuals, between non-smokers and current smokers or individuals with low *vs.* high PAL or low *vs.* high SB. (Table 4).

Compared with the average for all countries, the odds of dropping out were higher in participants from Ireland, whereas the odds in participants from the Netherlands were lower. Attrition was not significantly different for participants from Germany, Greece, Poland, Spain or the United Kingdom when compared with the overall average (Table 4). Being in an intermediate or routine/manual occupation, or being a student or retired/unemployed did not

significantly affect the OR of dropping out from the study compared with being in a professional/managerial occupation (Table 4). Baseline diet was not a predictor of drop out. Attrition did not differ significantly between individuals who met the recommendations for oily fish, wholegrains, red meat, fruit and vegetables and low-fat dairy products compared with those who did not (Table 4).

**Odds ratio of dropping out by behavioural characteristics**

As illustrated in **Figure 2**, the odds of dropping out were higher in participants who had signed up to the study with the aim of losing weight [1.53 (1.19-1.97); $P<0.001$]. Attrition was not significantly different if participants had, or had not, signed up with the aim of gaining weight, wanting to know what foods are best for them, wishing to improve their own or their family's health, for wellbeing reasons nor in individuals with an interest in sports performance or preventing a future illness (**Supplemental Table 2**).

Odds of attrition were higher if participants ate their main meal away from home [1.33 (1.04-1.72); $P=0.023$] and higher if they regularly skipped meals [1.75 (1.16-2.65; $P=0.008$; Figure 2]. ORs for dropping out were not significantly different depending on whether participants prepared a meal from scratch, ate many or few hot meals per day, or spent little time preparing a main meal (Supplemental Table 2).

Odds of dropping out were lower if participants reported that they frequently ate healthy [0.62 (0.45-0.86); $P=0.003$] and lower if they reported eating healthy without having to think about it consciously [0.74 (0.56-0.97); $P=0.031$; Figure 2]. Attrition was not significantly different depending on whether participants reported being in control of their health, staying healthy by taking care of themselves, agreed that efforts to improve their health were a waste of time, agreed that there was no use in concerning themselves with their health or felt weird if they did not eat healthily (Supplemental Table 2).

**Sensitivity analyses**

Factors predicting the likelihood of dropping out by month 3 were similar to those observed at month 6. However, odds of early attrition were higher if participants reported having a clinically diagnosed disease (Supplemental Table 2). Furthermore, odds of dropping out in overweight individuals were higher by month 3, compared with normal weight individuals. The odds of dropping out by month 3 were lower in individuals who indicated that they had

signed up to the study because they thought it was important to support academic studies, and lower among those who were curious to find out what happened in academic studies (Supplemental Table 2).

## DISCUSSION

The present study is the first to investigate the socio-demographic, anthropometric, dietary, behavioural and health-related characteristics of participants who dropped out of a 6-month internet-based study of PN. Our main findings suggest that dropouts were more likely to be younger, obese individuals who skip meals more often and were motivated by weight loss. Furthermore, more frequent data collection and PN feedback increased the likelihood of individuals dropping out.

The dropout rate observed in the present study is well within the range expected from a traditional face-to-face lifestyle intervention of this duration [29]. A recent meta-analysis on the effectiveness of web-based interventions [30] concluded that web-based interventions were as effective as face-to-face interventions in achieving weight loss and that the dropout rate was 21%, which is similar to the dropout rate in our study. However, the studies included in the meta-analysis were heterogeneous, with dropout rates as high as 40% [31; 32]. Our findings suggest that individuals interested in joining the Food4Me Study for the purpose of losing weight were more likely to drop out. The present study was not designed, or advertised, as a weight-loss study, but rather as a PN intervention aiming to improve diet and physical activity. Thus, some participants may have felt discouraged by their lack of weight loss during the intervention, which has been highlighted as a predictor of attrition in previous obesity-related studies [13; 33].

Our characterization of dropouts versus completers is broadly similar to previous lifestyle-based intervention studies. We found that younger age and higher BMI were strong predictors of greater attrition, which confirm previous findings [34; 35]. Older individuals may be more interested in sustained participation due to increased health concerns and heightened perceived susceptibility to disease. Obese individuals are often characterised by poor diet and low levels of physical activity [36], which may make lifestyle changes challenging. In contrast with an earlier report that individuals from lower socio-economic status (SES) are more likely to drop out of lifestyle interventions [7], we found no differences in attrition between occupation groups. This may be due to the personalised nature of the Food4Me intervention: recent research suggests that lifestyle interventions may be more effective in individuals with

low SES if they use tailored, or personalised, advice based on information about individual physical condition e.g. being overweight or having high cholesterol concentrations [37]. However, it may also be due to the higher SES of our participants and that our measure of SES was limited to occupation. We did not identify any difference in health and disease status between completers and those who dropped out. Although some associations between attrition and health-related characteristics have been observed [38], results have been inconsistent [39].

Inter-country differences in attrition observed in our analyses may partly be explained by the timing of the interventions. Ireland and the UK were the first centres to commence the Food4Me intervention, and so the higher dropout rates (although not significant for the UK) may be a result of initial teething problems, such as responding to queries from participants, in delivering the intervention, which were resolved when the other centres initiated recruitment. There is no obvious explanation for the significantly lower dropout rate in the Netherlands, but may have been due to centre-to-centre variation in the perseverance of researchers. Attrition was similar for control and PN intervention arms, however, individuals were more likely to drop out if they were in the high intensity feedback group. The burden associated with the higher number of occasions that participants were contacted to complete their FFQs and provide their phenotypic data between baseline and month 3 may explain these results more than receiving more frequent PN feedback per se. Alternatively, although individuals in the high intensity group had access to online discussion forums, personalised recipes and additional PA advice, while those in the low intensity group did not, the perceived value to participants of the more frequent feedback may not have been sufficient to outweigh the added burden of completing extra questionnaires. As a result, further consideration of the nature and frequency of such feedback may be important for future study designs.

Our study is the first internet-based PN study to characterise dropouts based on their dietary habits. Although many studies have associated socio-demographic characteristics, such as age and social class, with attrition [7; 14], behavioural determinants, such as reasons for participation and dietary habits, require further elucidation [8; 40]. Improved understanding of these factors may help in tailoring interventions to the needs of participants [9] and hence reduce dropout. Furthermore, a systematic review of predictors of dropout in weight loss interventions reported that poor eating habits were associated with higher dropout rates [8]. We found that participants were more likely to drop out if they skipped meals and if ate their

main meal away from home, suggesting that it may be more difficult for individuals with these dietary habits to comply with PN intervention. As a result, future design of PN advice would benefit from incorporating eating behaviour characteristics. Participants in the Food4Me Study were also less likely to drop out if they reported that they often ate healthily, did not have to consciously think about eating healthily and had lower PUFA and higher salt intakes. These findings are consistent with previous studies, where healthier individuals are more interested and willing to participate in and complete lifestyle interventions [8]. However, participants in the Food4Me PoP study were broadly representative of the European population in terms of obesity prevalence and dietary adequacies, and so would benefit from improved diet and PA [41]. Although psychological determinants of attrition have been studied [42; 43], the role of influences such as life stress, motivation and perceived self-efficacy on attrition in a PN intervention is poorly understood [44].

The present study had a number of strengths. The Food4Me PoP study included a large number of participants from 7 different European countries. By collecting information on socio-demographics, anthropometric, PA, and dietary intakes as well as information on dietary habits, we had a comprehensive overview of the characteristics of participants who dropped out of an internet-based PN intervention.

A limitation of this study is that psychological determinants of attrition were not investigated. Psychological constructs, such as perceived self-efficacy, may affect behaviour change and thus attrition. For example, an individual with a low perceived self-efficacy may be less likely to follow dietary advice and thus be less likely to remain in a dietary intervention [45]. However, as a PoP study, assessment of psychological determinants was not within the scope of the present study. As a result, the present findings should be interpreted with the understanding that psychological constructs may have played a role in determining attrition and further research into these specific determinants is warranted. A potential limitation of the study is that our data were self-reported via the internet, which may have introduced measurement error. However, the validity of internet-based, self-reported anthropometric data is high [46] and has been confirmed in the present study [47]. Dietary intakes were estimated by a FFQ, which is known to be subject to misreporting error [48] but this was minimised by validating our FFQ against a 4-day weighed food record [19]. Occupations were not asked for the purposes of SES and so the specificity of the classification of the occupations could not always be guaranteed. Our study participants were predominantly Caucasian so further

research among wider ethnicity groups is required to generalise our findings to other populations.

Our findings suggest that future PN interventions would benefit from strategies designed to sustain compliance from younger participants and those who are obese. Importantly, future PN interventions should consider dietary habits e.g. the frequency of meal skipping and eating main meals away from home, and psychological characteristics of their participants to develop strategies to help such participants remain in the study. In addition our finding of higher dropout rate among those completing more FFQs and receiving more frequent feedback suggests that the extra burden of completing additional questionnaires may be detrimental to their compliance with the intervention.

## Conclusions

Attrition in the Food4Me PN intervention study delivered via the internet was close to the average for other lifestyle-based interventions. There was no difference in dropout rate between those randomized to the Control group (generalised dietary advice) and those randomised to receive PN advice. However, more frequent data collection and PN feedback and behavioural barriers to healthy eating were strong determinants of attrition. Future PN interventions would benefit from improved strategies to minimise dropouts among younger and obese individuals. Findings from this study will be of value to researchers who wish to design and implement internet-delivered PN interventions which have considerable potential to deliver improved lifestyle behaviours and, therefore, benefits for public health.

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**Table 1** Baseline socio-demographic characteristics of participants who completed the intervention and those who dropped out by month 6

| | **Completers (n=1270)** | | **Dropouts (n=337)** | | **P*** |
|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | |
| Age, years | 40.8 | 13.0 | 34.8 | 12.3 | **<0.001** |
| Female, % | 57.4 | | 66.8 | | **0.017** |
| Ethnicity | | | | | |
| Caucasian, % | 96.9 | | 96.1 | | 0.83 |
| Occupation, % | | | | | |
| Professional and managerial | 40.0 | | 34.6 | | 0.53 |
| Intermediate occupations | 26.1 | | 25.5 | | 0.98 |
| Routine and manual | 9.5 | | 11.1 | | 0.42 |
| Student | 14.0 | | 21.2 | | 0.13 |
| Retired | 3.0 | | 2.4 | | 0.39 |
| Unemployed | 7.4 | | 5.3 | | 0.88 |
| Anthropometrics | | | | | |
| Body weight, kg | 74.6 | 15.7 | 75.4 | 17.0 | **<0.001** |
| BMI, kg/m$^2$ | 25.4 | 4.8 | 25.9 | 5.5 | **<0.001** |
| Waist circumference, cm | 85.9 | 13.7 | 84.6 | 14.7 | **0.015** |
| Height, m | 1.7 | 0.1 | 1.7 | 0.1 | 0.89 |
| Physical activity | | | | | |
| PAL | 1.7 | 0.2 | 1.7 | 0.2 | 0.86 |
| Sedentary behaviour, min/d | 747 | 75.2 | 732 | 77.1 | 0.31 |
| Dietary conditions, % | | | | | |
| Want to lose weight | 45.8 | | 53.7 | | **0.002** |
| Restricted diet | 6.7 | | 8.3 | | 0.66 |
| Medication use, % | | | | | |
| Prescribed medication | 30.5 | | 27.6 | | 0.67 |
| Non-prescribed medication | 10.3 | | 7.7 | | 0.32 |
| Health and disease | | | | | |
| Total cholesterol, mmol/L | 4.6 | 1.0 | 4.3 | 0.9 | 0.06 |
| Current smoker, % | 11.7 | | 13.7 | | 0.66 |
| Cancer, % | 1.6 | | 0.3 | | 0.21 |
| High blood pressure, % | 7.9 | | 6.8 | | 0.21 |
| Heart disease, % | 1.4 | | 1.2 | | 0.61 |
| Diabetes, % | 0.6 | | 0.6 | | 0.61 |
| Blood disorders, % | 1.1 | | 0.6 | | 0.29 |

Values represent means, SD or percentages; BMI, body mass index; PAL, Physical activity level

*, Multiple linear regression and logistic regression were used to test for significant differences between groups in continuous and categorical variables, respectively. Analyses were adjusted for age, sex and country.

**Table 2** Baseline dietary characteristics of participants who completed the intervention and those who dropped out by month 6

| | **Completers (n=1270)** | | **Dropouts (n=337)** | | **P*** |
|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | |
| Nutrient intake | | | | | |
| Total energy, kcal/d | 2756 | 1208 | 2796 | 1149 | 0.43 |
| EI:BMR ratio | 1.8 | 0.7 | 1.8 | 0.7 | 0.94 |
| Total fat, % energy | 35.5 | 6.5 | 35.1 | 6.5 | 0.29 |
| SFA, % energy | 14.0 | 3.4 | 14.1 | 3.6 | 0.64 |
| MUFA, % energy | 13.6 | 3.5 | 13.2 | 3.2 | 0.10 |
| PUFA, % energy | 5.7 | 1.5 | 5.4 | 1.2 | **0.002** |
| Protein, % energy | 16.9 | 3.6 | 17.1 | 4.1 | 0.41 |
| Carbohydrate, % energy | 46.8 | 8.2 | 47.3 | 8.3 | 0.70 |
| Sugars, % energy | 21.2 | 6.1 | 21.0 | 6.7 | 0.21 |
| Dietary fibre, g/d | 33.2 | 18.9 | 33.9 | 20.6 | 0.35 |
| Salt, g/d | 8.1 | 4.2 | 8.6 | 7.9 | **0.050** |
| Meeting dietary recommendations, % | | | | | |
| Oily fish | 34.7 | | 32.3 | | 0.92 |
| Wholegrains | 77.6 | | 75.7 | | 0.74 |
| Red meat | 48.0 | | 49.6 | | 0.67 |
| Fruit and vegetables | 57.7 | | 56.4 | | 0.66 |
| Low fat dairy | 8.0 | | 6.5 | | 0.29 |

Values represent means, SD or percentages; SFA, saturated fatty acid; MUFA, mono-unsaturated fatty acid; PUFA, poly-unsaturated fatty acid

*, Multiple linear regression and logistic regression were used to test for significant differences between groups in continuous and categorical variables, respectively. Analyses were adjusted for age, sex and country.

**Table 3** Odds ratio (OR) of participants dropping out at month 6 by intervention arm

| | **Odds ratio** | **95% CI** | **P*** |
|---|---|---|---|
| Control (ref) vs. | | | |
| L1 (low and high intensity) | 1.40 | 0.99-1.98 | 0.05 |
| L2 (low and high intensity) | 1.04 | 0.72-1.48 | 0.85 |
| L3 (low and high intensity) | 1.07 | 0.75-1.53 | 0.70 |
| Control (ref) vs. personalised nutrition | 1.17 | 0.87-1.56 | 0.30 |
| Low (ref) vs. high intensity feedback | 1.81 | 1.36-2.41 | **<0.001** |

Values represent the adjusted OR, 95% CI and their corresponding P value. L1, Level 1 – personalised advice based on diet alone, L2, Level 2 – personalised advice based on diet and phenotype, L3, personalised advice based on diet, phenotype and genotype

*, Logistic regression was used to test for significant differences between groups. Analyses were adjusted for age, sex and country.

**Table 4** Odds ratio (OR) for participants dropping out at month 6 by baseline socio-demographic characteristics and dietary adequacies

| | **Odds ratio** | **95% CI** | **P*** |
|---|---|---|---|
| Under 45 y (ref) vs. over 45 y | 2.57 | 1.95-3.39 | **<0.001** |
| Male (ref) vs. female | 1.38 | 1.06-1.78 | **0.015** |
| BMI category (ref normal weight) | | | |
| Overweight | 1.31 | 0.91-1.90 | 0.15 |
| Obese | 2.25 | 1.47-3.43 | **<0.001** |
| Non-smoker (ref) vs. current smoker | 1.11 | 0.86-1.44 | 0.41 |
| Country (ref overall average) | | | |
| Germany | 1.09 | 0.76-1.56 | 0.66 |
| Greece | 0.90 | 0.63-1.27 | 0.54 |
| Ireland | 1.62 | 1.20-2.18 | **0.002** |
| Netherlands | 0.18 | 0.09-0.35 | **<0.001** |
| Poland | 1.08 | 0.77-1.50 | 0.67 |
| Spain | 1.06 | 0.75-1.52 | 0.73 |
| United Kingdom | 1.17 | 0.85-1.62 | 0.33 |
| Occupation (ref professional and managerial) | | | |
| Intermediate occupations | 1.08 | 0.73-1.59 | 0.70 |
| Routine and manual | 1.22 | 0.73-2.08 | 0.45 |
| Student | 0.73 | 0.45-1.17 | 0.19 |
| Retired or unemployed | 1.37 | 0.75-2.52 | 0.31 |
| Meeting dietary recommendations (ref not meeting recommendation) | | | |
| Fruit and vegetables (≥5 portions/day) | 1.05 | 0.82-1.35 | 0.69 |
| Wholegrains (≥50g/day) | 0.93 | 0.70-1.24 | 0.63 |
| Red meat (≤3 servings/week) | 0.93 | 0.72-1.20 | 0.56 |
| Oily fish (≥1 serving/week) | 0.99 | 0.77-1.31 | 0.99 |
| Low-fat dairy products (≥3 servings/day) | 0.77 | 0.48-1.26 | 0.30 |

Values represent the adjusted OR, 95% CI and their corresponding P value.

*, Logistic regression was used to test for significant differences between groups. Analyses were adjusted for age, sex and country

## FIGURE LEGENDS

**Figure 1** Flow diagram of cumulative dropouts from the Food4Me Proof of Principle Study

**Figure 2** Odds ratio (OR) for participants dropping out according to their dietary behaviours and reasons for participation in the study at baseline[1]

Values represent the adjusted OR, 95% CI and their corresponding P value.

1, Logistic regression was used to test for significant differences between groups. Models were adjusted for age, sex and country. Variables are dichotomous, reference group ("No/Disagree").

Supplemental Table 1. Screening questionnaire on dietary habits and reasons for interest in the study

| **Question** | **Response options** | **Aggregated response** |
|---|---|---|
| How often do you eat your main meal away from home?<br>How many hot or cooked meals do you normally eat per day? | Never or up to once/ month<br>Two to three times/ month<br>Once per week<br>Twice or more/ week | Rarely<br>Often |
| How often do you prepare a meal "from scratch"? | Every day<br>4-6 times per week<br>1-3 times per week | Often<br>Rarely |
| Do you skip meals and replace them with snacks? | (Almost) never | Often<br>Rarely |
| How much time on average do you spend preparing a main meal? | Less than 10 min<br>10-20 min<br>20-30 min<br>Up to an hour<br>Over an hour | Less than 30 min<br>More than 30 min |
| I can be as healthy as I want to be<br>I am in control of my health<br>I can pretty much stay healthy by taking care of myself<br>Efforts to improve your health are a waste of time<br>I am bored by all the attention that is paid to health and disease prevention<br>What's the use of concerning yourself about your health - you'll only worry yourself to death<br>Eating healthily is something I do frequently<br>I eat healthily without having to consciously think about it<br>I feel weird if I don't eat healthily | Completely disagree<br>Disagree<br>Neither disagree nor agree<br>Agree<br>Completely agree | Disagree<br>Neither disagree nor agree<br>Agree<br>Note that the option 'Neither disagree nor agree' was excluded in the data analysis |
| I'm interested in personalised nutrition<br>I want to know what foods are best for me<br>I want to lose weight<br>I want to gain weight<br>I want to improve my family's health<br>I want to improve my health | No<br>Yes | No<br>Yes |

| | | |
|---|---|---|
| I want to improve my wellbeing | | |
| I want to improve my sports performance | | |
| I want to prevent a future illness | | |
| I have a family history of diet-related illness | | |
| I think it is important to help academic studies | | |
| I am curious to find out what happens in these studies | | |
| I can manage to stick to healthful foods: even if | Very uncertain | Not certain |
| I need a long time to develop the necessary routines | Rather uncertain<br>Rather certain | Certain |
| I can manage to stick to healthful foods: even if | Very certain | |
| I have to try several times until it works | | |
| I can manage to stick to healthful foods: even if | | |
| I have to rethink my entire way of nutrition | | |
| I can manage to stick to healthful foods: even if | | |
| I do not receive a great deal of support from others when making my first attempts | | |
| I can manage to stick to healthful foods: even if | | |
| I have to make a detailed plan | | |

Supplemental Table 2. Odds ratio of participants dropping out by dietary habits and reasons for interest in the study

| Question | Odds ratio | 95% CI | P* |
|---|---|---|---|
| Eat your main meal away from home often (ref rarely) | 1.33 | 1.04-1.72 | **0.023** |
| Normally eat many hot or cooked meals eat per day (ref rarely) | 1.06 | 0.82-1.37 | 0.67 |
| How often do you prepare a meal "from scratch" (ref often) | 1.03 | 0.79-1.34 | 0.82 |
| Do you skip meals and replace them with snacks (ref rarely) | 1.75 | 1.16-2.65 | **0.008** |
| Time spent preparing a main meal (ref less than 30 min) | 0.96 | 0.75-1.24 | 0.78 |
| I can be as healthy as I want to be (ref disagree) | 0.95 | 0.62-1.44 | 0.79 |
| I am in control of my health (ref disagree) | 0.87 | 0.58-1.29 | 0.48 |
| I can pretty much stay healthy by taking care of myself (ref disagree) | 0.91 | 0.50-1.65 | 0.75 |
| Efforts to improve your health are a waste of time (ref disagree) | 1.65 | 0.78-3.48 | 0.19 |
| I am bored by all the attention that is paid to health and disease prevention (ref disagree) | 1.30 | 0.58-2.94 | 0.53 |
| What's the use of concerning yourself about your health - you'll only worry yourself to death (ref disagree) | 1.31 | 0.74-2.33 | 0.35 |
| Eating healthily is something I do frequently (ref disagree) | 0.62 | 0.45-0.86 | **0.003** |
| I eat healthily without having to consciously think about It (ref disagree) | 0.74 | 0.56-0.97 | **0.031** |
| I feel weird if I don't eat healthily (ref disagree) | 1.04 | 0.77-1.41 | 0.81 |
| I'm interested in personalised nutrition (ref no) | 0.94 | 0.71-1.24 | 0.65 |
| I want to know what foods are best for me (ref no) | 0.86 | 0.64-1.15 | 0.31 |
| I want to lose weight (ref no) | 1.53 | 1.18-1.97 | **0.001** |
| I want to gain weight (ref no) | 1.32 | 0.60-2.95 | 0.49 |
| I want to improve my family's health (ref no) | 0.96 | 0.72-1.28 | 0.77 |
| I want to improve my health (ref no) | 0.99 | 0.77-1.28 | 0.97 |
| I want to improve my wellbeing (ref no) | 1.23 | 0.96-1.6 | 0.11 |
| I want to improve my sports performance (ref no) | 1.09 | 0.85-1.41 | 0.49 |
| I want to prevent a future illness (ref no) | 1.08 | 0.84-1.39 | 0.55 |
| I have a family history of diet-related illness (ref no) | 0.81 | 0.52-1.25 | 0.34 |
| I think it is important to help academic studies (ref no) | 0.80 | 0.62-1.03 | 0.09 |
| I am curious to find out what happens in these studies (ref no) | 0.82 | 0.64-1.05 | 0.11 |
| I can manage to stick to healthful foods: even if I need a long time to develop the necessary routines (ref no) | 0.99 | 0.61-1.62 | 0.98 |
| I can manage to stick to healthful foods: even if I have to try several times until it works (ref no) | 0.76 | 0.45-1.30 | 0.31 |
| I can manage to stick to healthful foods: even if I have to rethink my entire way of nutrition (ref no) | 1.16 | 0.80-1.68 | 0.43 |
| I can manage to stick to healthful foods: even if I do not receive a great deal of support from others when making my first attempts (ref no) | 0.76 | 0.55-1.05 | 0.10 |

| | | | |
|---|---|---|---|
| I can manage to stick to healthful foods: even if I have to make a detailed plan (ref no) | 0.81 | 0.56-1.15 | 0.24 |

Values represent the adjusted OR, 95% CI and their corresponding P value.

*, Logistic regression was used to test for significant differences between groups. Models were adjusted for age, sex and country. Variables are dichotomous.

## Supplementary Methods

The following text is an excerpt from the full manuscript detailing the study design and baseline characteristics of the Food4Me randomized controlled trial (RCT) (1) and has been republished with the kind permission of Springer-Verlag.

## Study design

The Food4Me Proof of Principle (PoP) study was a four-arm, web-based RCT conducted across seven European countries, which compared the effects of different levels of personalised nutrition (PN) on health-related outcomes. The intervention was designed to emulate a real-life web-based PN service, and the study aimed to answer the following primary research questions:

- Does personalisation of dietary advice assist and/or motivate participants to eat a healthier diet in comparison with non-personalised, conventional healthy eating guidelines?
- Is personalisation based on individualised phenotypic or genotypic information more effective in assisting and/or motivating study participants to make, and to sustain, appropriate healthy changes, than personalisation based on diet alone?

To answer these research questions, we used an hierarchical study design in participants randomised to a control group (Level 0) or to one of 3 PN interventions with increasingly complex bases for personalised dietary advice (Levels 1–3), i.e. randomisation was to one of the following treatment groups for a 6-month period:

- Level 0 (L0): (control group): non-personalised dietary advice based on (European) population healthy eating guidelines.
- Level 1 (L1): personalised dietary advice based on individual dietary intake data alone.
- Level 2 (L2): personalised dietary advice based on individual dietary intake and phenotypic data.
- Level 3 (L3): personalised dietary advice based on individual dietary intake, phenotypic and genotypic data.

The secondary research question of the study was as follows:

- Does more frequent feedback help participants to improve their compliance and motivate them to eat a healthier diet and follow a healthier lifestyle in comparison with those receiving less frequent feedback?

To answer this secondary research question, participants randomised to Levels 1, 2 or 3 were further randomised into “low-intensity” or “high-intensity” intervention groups:

- Low intensity: personalised feedback given three times during the intervention (at baseline, month 3 and month 6).
- High intensity: personalised feedback given five times during the intervention (at baseline and months 1, 2, 3 and 6). In addition, the “high-intensity” group had access to an online forum for discussion of topics related to the intervention, had access to personalised recipes and had more personalised physical activity (PA) feedback.

**Primary and secondary outcomes**

The primary outcome of the study was dietary intake at months 3 and 6. The secondary outcomes included PA and phenotypic biomarkers at months 3 and 6. The latter included obesity-related measures (i.e. body weight, body mass index (BMI) and waist circumference) and blood-based biomarkers (i.e. blood glucose, total cholesterol, carotenoids and fatty acids).

**Recruitment**

Participants were recruited via the Internet to emulate a web-based PN service. This was aided by local and national advertising of the study via the Internet, radio, newspapers, posters, e-flyers, social media and word of mouth.

Recruitment into the Food4Me intervention trial was carried out using identical standardised protocols in seven European recruitment centres. Based on sample size calculations (see below for further details), we aimed to recruit a total of 1,540 study participants (i.e. 220 participants per country). The PoP study recruitment sites were as follows: University

College Dublin, Ireland; Maastricht University, the Netherlands; University of Navarra, Spain; Harokopio University, Greece; University of Reading, UK; National Food and Nutrition Institute, Poland; and Technische Universität München, Germany.

**Eligibility criteria**

Participants aged ≥18 years of age were included in the study. To keep the cohort as representative as possible of the adult population, the following minimal sets of exclusion criteria were applied:

- Pregnant or lactating;
- No or limited access to the Internet;
- Following a prescribed diet for any reason, including weight loss, in the last 3 months;
- Diabetes, coeliac disease, Crohn's disease, or any metabolic disease or condition altering nutritional requirements such as thyroid disorders (if condition was not controlled), allergies or food intolerances.

Exclusion based on prescribed diet or specific diseases was to avoid the theoretical risk that participating in the study could be disadvantageous to the individual.
Ethical approval and participant consent

The Research Ethics Committees at each University or Research Centre delivering the intervention granted ethical approval for the study. An application for the Norwegian arm of the study administered by the University of Oslo was not approved by the local ethics committee.

Prior to participation, an information sheet was provided to all potential volunteers who completed an online informed consent form before submitting personal data. This signed online consent form was automatically directed to the study coordinator to be counter-signed and archived. A second online informed consent form was completed before randomisation to the intervention study only for participants who met the inclusion criteria. A two-step consenting process was applied to permit collection of socio-demographic and dietary information for those interested in participating in PN even if they were ineligible for enrolment in this study, e.g. because of prescribed diets or food allergies. All Ethical

Committees accepted an online informed consent procedure, except for the Netherlands and Germany whose ethics committees requested an additional written informed consent form for each participant recruited into the study. This hard copy consent form was returned by the participant to the respective recruitment centre.

**Intervention design**

Eligible and consenting participants were allocated to one of the four arms of the study, which included three intervention groups receiving different levels of personalised nutritional advice (L1: dietary data only; L2: dietary and phenotypic data; and L3: dietary, phenotypic and genotypic data) and the control group (L0), receiving conventional, non-personalised advice. To address our secondary research question, participants in levels L1, L2 and L3 were allocated into "low-" or "high-"intensity groups (see next section for details of the randomisation methods). At the end of the study (month 6), all participants received a personalised report which contained dietary, phenotypic and genotypic information and which summarised changes in their individual dietary intake and phenotypic measures between baseline and month 6 of the intervention.

**Randomisation**

Participants were randomised to one of the seven treatment groups (control group (L0), L1 high intensity, L1 low intensity, L2 high intensity, L2 low intensity, L3 high intensity and L3 low intensity) in combination with stratified randomisation by country (UK, Greece, Spain, Poland, Ireland, Germany and the Netherlands), sex (female or male) and age (<45 or ≥45 years) equally allocated to each treatment using an urn randomisation scheme (2).
Intervention groups

Level 0 ("control group")

Following baseline measures, participants randomised to the control group (L0) received non-personalised dietary advice based on conventional population healthy eating guidelines. This non-personalised dietary advice was based on national dietary recommendations in each of the seven European countries participating in the Food4Me PoP Study which were integrated to produce a coherent set of recommendations suitable for Europe-wide use. These

"standardised" recommendations included advice on energy intake to optimise BMI and on the consumption of fruits and vegetables, whole-grain products, fish, dairy products, meat, type of fat and salt. In addition, these recommendations included a generic PA recommendation. An advice leaflet was delivered via the web and also attached to an e-mail, which was sent to participants at baseline and at month 3 of the study.

Level 1 ("diet group")

Following baseline measures, participants randomised to L1 received feedback on how their intakes of specific food groups (fruits and vegetables, whole-grain products, fish, dairy products and meat) compared with guideline amounts. In addition, personalised dietary advice based on their reported dietary intake at baseline and month 3.

Level 2 ("diet + phenotype group")

Following baseline measures, participants randomised to L2 received personalised dietary advice based on their dietary intake (as for L1) and also on their baseline phenotypic data. The phenotypic feedback was based on anthropometric measurements and nutrient- and metabolic-related biomarkers.

Level 3 ("diet + phenotype + genotype group")

Participants randomised to L3 received personalised dietary advice based on their dietary intake plus phenotypic and genotypic data collected at baseline. The genotypic feedback was based on specific variants in five nutrient-responsive genes selected specifically for the study.

**Personalised feedback report**

Participants randomised to L1, L2 and L3 received personalised feedback based on decision trees developed to provide a structured, evidence-based protocol for delivering tailored advice. This advice was based on dietary, PA, phenotypic and genotypic information as appropriate for each intervention group. In each case, intakes were compared with recommended intakes and determined to be adequate, high or low. If intakes were categorised as too high or too low, contributing foods were identified and specific messages were

developed to advise change in intake of those foods. Full details of these decision trees will be published elsewhere. Protocols for the decision trees were standardised across the seven recruitment centres and translated into the language of each country. Nutritionists and dietitians implementing the decision trees were trained to ensure consistency in the PN advice given throughout the study, and, across all seven countries, these staff participated in frequent teleconferences (every 1–2 weeks) to resolve issues and to share best practice.

The participants' reports contained information on how their health-related characteristics compared with recommendations. Estimations of healthy behaviours were explained using a three-colour sliding scale: green representing "Good, no change recommended", amber representing "Improvement recommended" and red representing "Improvement strongly recommended". For the genotype-based information, risk was indicated using "Yes" or "No" according to whether the participant did, or did not, carry the higher risk variant for each of the five nutrient-related genes. Finally, each report contained a personalised message from the dietitian/nutritionist to the participant. This message provided tailored advice for body weight and PA, and included specific nutrition-related goals derived from dietary, phenotypic and/or genotypic markers (according to the participants' intervention group). Based on patient-centred counselling models for facilitating dietary change (3), a total of three nutrient-related goals were provided. These goals were selected by ranking all dietary, phenotypic and genotypic markers (as appropriate for the intervention group) based on their risk status (red, amber or green). The cut-off points for each of the nutritional and phenotypic variables were used to derive personalised goals and advice.

**Behavioural change techniques**

Explicit behaviour change techniques (BCT) were integrated into several aspects of the intervention and used to support, encourage and enhance dietary and lifestyle changes. The BCT and their conceptual framework were derived from work by Michie et al. on smoking cessation and dietary behaviour change (4, 5). The BCT categories used in the Food4Me PoP study were as follows: (1) behaviour and motivation, (2) behaviour and self-regulatory capacity/skills, (3) interaction and delivery, (4) interaction and information gathering and (5) interaction and communication.

**Study measures**

Participants consented to self-report all their measures via the Internet and to send requested biological samples (Dry Blood Spot cards and buccal swabs) by conventional mail, using prepaid, stamped addressed envelopes provided by the research team. To ensure that procedures were similar in all recruiting centres, standardised operating procedures were prepared for all study procedures (see below), and researchers underwent centralised training. In addition, to enable participants to collect and report the required information and to collect, process and dispatch the necessary biological samples correctly, participants were provided with detailed instructions online, including pictures and video demonstrations of all procedures, in their native language.

First screening questionnaire

Participants who consented to take part in the study completed an online screening questionnaire that included basic socio-demographic and health statistics, and information about Internet access, pregnancy and lactation, prescribed diets, food intolerance and allergies (used as exclusion criteria). Persons who were deemed unsuitable for the study, e.g. because of inadequate Internet access, pregnancy or use of a therapeutic diet, received formal e-mail notification that they did not match the inclusion criteria for the study and were thanked for their time.

Second screening questionnaire

Eligible participants for inclusion in the RCT completed a second online questionnaire, which collected more detailed socio-demographic, health and anthropometric data, as well as detailed information on food choices and dietary habits using a Food Frequency Questionnaire (FFQ) developed and validated specifically for this study (see below). Following assessment of this information, participants considered suitable for inclusion in the intervention study were asked to complete a second online consent form, which was sent to the study coordinator to be signed and archived. Potential participants considered unsuitable for the intervention study, e.g. through non-compliance in completion of the screening FFQ, received formal notification that they did not match the inclusion criteria for the study and were thanked for their time.

## Anthropometric measurements

Body weight, height and upper thigh, waist and hip circumferences were self-measured and self-reported by participants via the Internet. Standardised instructions on how to perform these measurements were provided in printed and digital format (i.e. a video clip available on the Food4Me website in the languages of each of the seven recruitment countries). Participants were instructed to measure body weight without shoes and wear light clothing using a home or commercial scale and to measure height barefoot using a standardised measuring tape provided by Food4Me. Waist circumference was measured at the mid-point between the lower rib and the iliac crest using the same tape measure. Hip circumference was measured at the widest point around the greater trochanters, while the upper thigh circumference was measured midway between the iliac crest and the knee.

## Food Frequency Questionnaire (FFQ)

Habitual dietary intake was quantified using an online-FFQ, developed for this study which included food items consumed frequently in each of the seven recruitment countries. The Food4Me online-FFQ has been validated against a 4-day weighed food record, and the agreement between methods varied, with correlations ranging from .23 (vitamin D) to .65 (protein, % total energy) for nutrient intakes and .11 (soups, sauces and miscellaneous foods) to .73 (yogurts) for food group intake (6, 7). Intakes of foods and nutrients were computed in real time using a food composition database based on McCance & Widdowson's "The composition of foods" (8).

## Metabolic markers

Finger-prick blood samples were collected by participants using a collection pack provided by Vitas Ltd, Oslo, Norway. To help with blood collection, participants had access to an online video demonstration with instructions and frequently asked questions. Each participant was asked to fill two Dry Blood Spot cards (equivalent to five drops of blood or to 150 µl of blood per card) at each collection time point. When the ten blood spots were filled, participants were instructed to dry the cards at room temperature for at least 2 h, but not longer than 4 h, before samples were put in an airtight aluminium bag with drying sachet and returned by post to the corresponding recruiting centre. The centres shipped the samples to

Vitas (Vitas Ltd, Norway) and DSM (DSM Nutritional Products Ltd, Switzerland) for measurements of glucose, total cholesterol, carotenoids, n-3 fatty acid index and 32 other fatty acids (by Vitas), and vitamin D (25-OH D2 and 25-OH D3) (by DSM).

Genotypic analyses

Buccal cell samples were collected by participants at baseline using Isohelix SK-1 DNA buccal swabs and Isohelix Dri-capsules and returned by post to each recruiting centre for shipment to LCG Genomics (Hertfordshire, UK). LCG Genomics undertook DNA extraction and genotyping of the five loci used for derived personalised advice. These loci were analysed using KASPTM genotyping assays to provide bi-allelic scoring of single nucleotide polymorphisms (SNPs) and insertions and deletions at specific loci.

Physical activity

PA patterns were determined using a PA monitor—the DirectLife triaxial accelerometer for movement registration (TracmorD) (Philips Consumer Lifestyle, the Netherlands)—and a self-reported Baecke PA questionnaire (9) which was completed online. The accelerometer-based monitor (Philips DirectLife Activity Monitor, the Netherlands) was posted to each participant. Online video demonstrations as well as digital and printed instructions were provided at baseline. Participants were instructed to wear the monitor throughout the six-month intervention and to upload their PA data fortnightly via an online interface.

Sample size consideration

A power calculation was conducted a priori using Minitab® (version 16.1.0) and data for n-3 fatty acids and glucose concentrations in adult European populations. To address our primary research questions, and based on the resources available for the intervention, a sample size of n = 326 participants for each of the four intervention arms was planned. This allows us to detect differences of 0.22 SD in our main outcomes with 80 % power and alpha = 0.05. Assuming that the population standard deviation (SD) for n-3 fatty acid index is 1.5 units and for glucose is 1.05 mmol l−1, a total sample of n = 1,280 participants was estimated as sufficient to detect a real differences of 0.33 units for n-3 PUFA and 0.23 mmol l−1 glucose post-intervention. Allowing for a potential 20 % drop out, we aimed to recruit 1,540 participants into the study (220 participants per centre).

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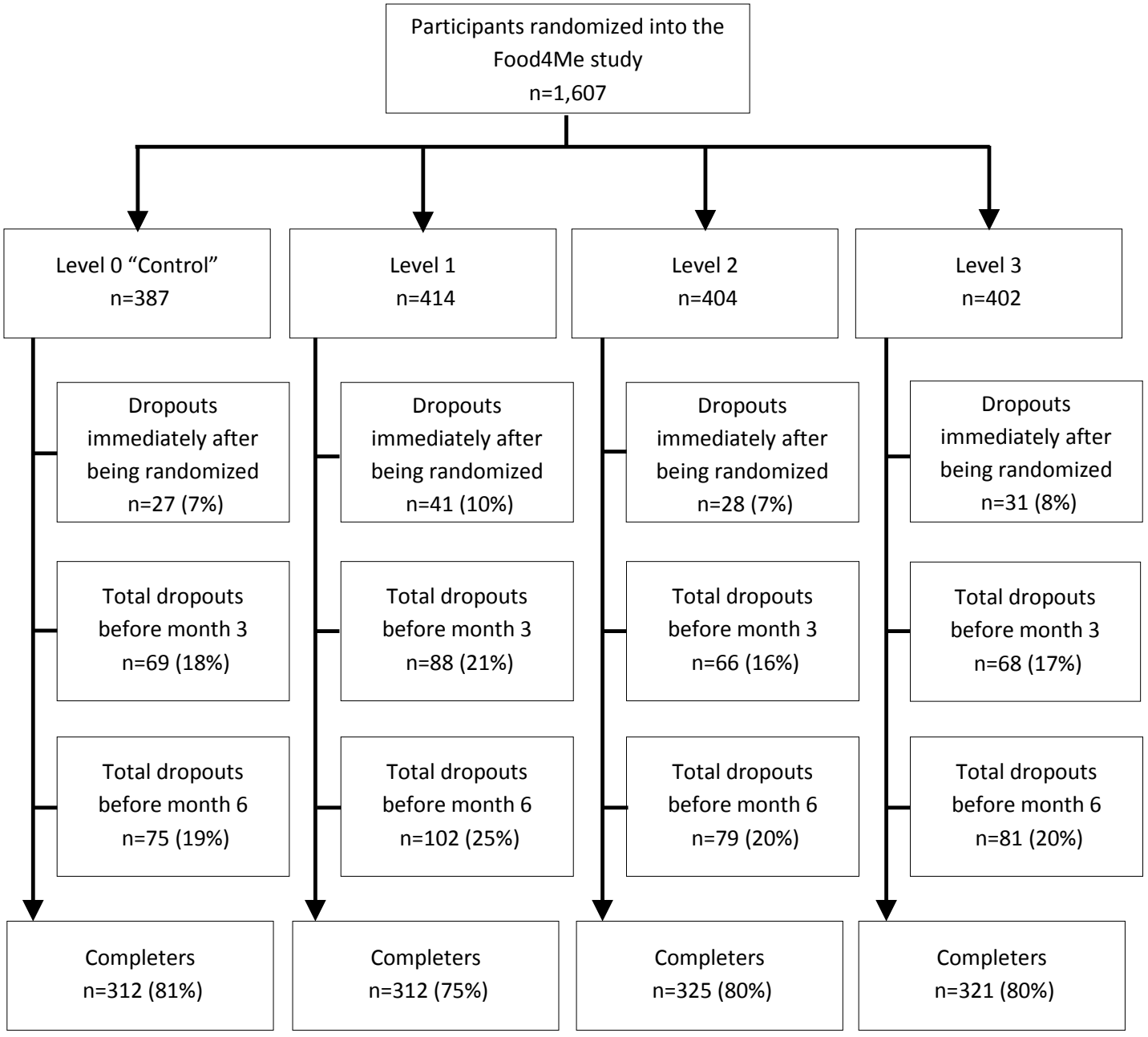
Participants randomized into the Food4Me study n=1,607
Level 0 "Control" n=387
Level 1 n=414
Level 2 n=404
Level 3 n=402
Dropouts immediately after being randomized n=27 (7%)
Dropouts immediately after being randomized n=41 (10%)
Dropouts immediately after being randomized n=28 (7%)
Dropouts immediately after being randomized n=31 (8%)
Total dropouts before month 3 n=69 (18%)
Total dropouts before month 3 n=88 (21%)
Total dropouts before month 3 n=66 (16%)
Total dropouts before month 3 n=68 (17%)
Total dropouts before month 6 n=75 (19%)
Total dropouts before month 6 n=102 (25%)
Total dropouts before month 6 n=79 (20%)
Total dropouts before month 6 n=81 (20%)
Completers n=312 (81%)
Completers n=312 (75%)
Completers n=325 (80%)
Completers n=321 (80%)

**Figure 1**

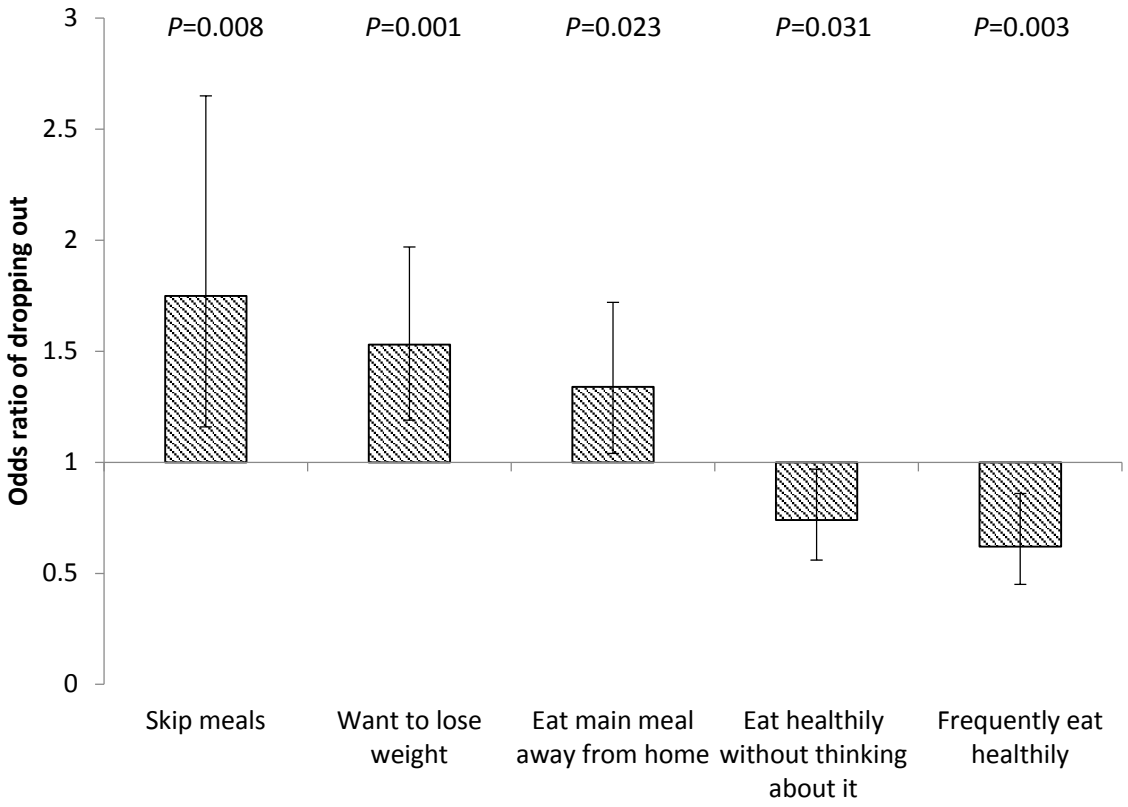
3
2.5
2
1.5
1
0.5
0
Odds ratio of dropping out
P=0.008
P=0.001
P=0.023
P=0.031
P=0.003
Skip meals
Want to lose weight
Eat main meal away from home
Eat healthily without thinking about it
Frequently eat healthily

Figure 2